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RESPONSE TO U.S. EPA LABORATORY AUDIT

04/17/91

DOE-1085-91
DOE-FSO/USEPA
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LETTER

Department of Energy
FMPC Site Office
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APR 17 1991

DOE-1085-91

Ms. Catherine A. McCord
Remedial Project Director
U. S. Environmental Protection Agency
Region V - 5HR-12
230 South Dearborn Street
Chicago, IL 60604

Dear Ms. McCord:

RESPONSE TO U. S. EPA LABORATORY AUDIT

References: 1) Letter, C. A. McCord to A. P. Avel, "Lab Audit U. S. DOE Fernald OH6 890 008 976," dated November 13, 1990

2) Letter, DOE-226-91, A. P. Avel to C. A. McCord, "Laboratory Audit Follow-Up Response," dated November 7, 1990

3) Letter, DOE-68-91, A. P. Avel to C. A. McCord, "Laboratory Audit Response," dated October 12, 1990

4) Letter, C. A. McCord to B. Davis, "Audit and Data Validation of Environmental Samples of Radiological and Chemical Analyses U. S. DOE-Fernald OH6 890 008 976," dated September 13, 1990

The enclosure accompanying this letter provides the specific responses requested to the findings of the U. S. EPA audit of the IT Corporation Laboratory, utilized for the analysis of samples collected in support of the FMPC RI/FS (reference letters 1 and 4). This fulfills the commitment made to you in references 2 and 3.

Although this response was prepared in November, 1990, a decision was made to validate the laboratory provided responses prior to releasing them. This audit was conducted by WMCO earlier this year and the results were recently obtained.

If you have any questions concerning this transmittal, please contact Oba Vincent at FTS 774-6937.

Sincerely,

Jack R. Craig
FMPC Remedial Action
Project Director

FSO:Vincent

Enclosure: As stated

cc w/encl.:

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DETAILED RESPONSE TO U. S. EPA AUDIT OF THE IT OAK RIDGE LABORATORY

The following detailed responses to specific laboratory quality control concerns are provided in the order presented in the enclosure to your audit report. In addition, concerns relating to the validation of Round One and Four samples are specifically addressed.

LABORATORY AUDIT:

The first finding states that 18 out of 70 positions are vacant, and that the QC Coordinator and QC Technician positions are vacant within the Radiological Laboratory. ITAS-Oak Ridge has filled the position of QC Coordinator for the Radiological Laboratory and is currently seeking an additional QC Technician. The open positions on the organizational chart are used to identify positions for planned expansion. IT attempts to keep key positions filled through the identification of backup personnel to fill those slots should they become open.

The second finding states that there is no SOP for the screening of mixed-waste samples. There has been a screening procedure (RSL-1002) in use since May 1987 that describes the flow of screening aliquots and the results. A new revision to the screening procedure detailing preparation of screens is being circulated for review at this time.

A third finding states that no internal-blind Performance Evaluation (PE) samples have been run since September 1988. Internal single-blind PE samples have been submitted on a semi-annual basis by the Mixed Waste Laboratory since 1989 and annually prior to that time for the purpose of training. The Radiological Laboratory has submitted these annually for training purposes. Internal double-blind PE samples have been submitted at least quarterly by both laboratories since 1989.

The fourth finding states that the Radiological Laboratory has not conducted monthly surveillances since March 22, 1989. This problem has been resolved with the hiring of the Radiological QC Coordinator in November 1989. Monthly surveillances have been performed since that time.

The fifth finding states that some nonconformances are not being closed out in a timely fashion. Both Mixed-Waste and Radiological Laboratories utilize a Nonconformance Logbook with corrective action target dates specified. The QC Coordinators for both laboratories also issue reports at least quarterly to management listing outstanding nonconformances. These systems have resulted in the timely closure of most nonconformances.

The sixth finding applies to SOPs. SOPs that are in need of revision have been identified (through Laboratory Surveillance 90S-8). Revisions are currently being generated. The laboratories will not use flow charts since the format for SOPs has been determined on the corporate level. Revisions to Mixed-Waste Laboratory SOPs are not issued with change pages but as complete revisions. The Radiological procedures use change pages as stated in the letter. This practice will continue since there have been no observed

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deviations from these SOPs that can be traced to the use of change pages. The SOP for radiostrontium will be rewritten to allow the option of sequential separation of Sr89 and Sr90, or the rapid analysis of strontium for total strontium.

The seventh finding states that the Laboratory Health and Safety Manual needs to be an ongoing continuing priority. The Laboratory is continuing to generate health and safety procedures through the generation of SOPs as a part of the Radiological Procedures Manual (2600 Series). If in the future these procedures warrant a manual exclusive to them, one will be issued. In addition, the Laboratory utilizes the corporate 9000 Series of Health and Safety, which is applicable to all Laboratory projects.

DATA VALIDATION RESULTS OF ROUND ONE SAMPLES:

Inorganic Analyses

The finding listed in the first paragraph states that the Laboratory did not run interference check samples, laboratory control samples, and serial dilutions. The laboratory now includes these samples at the required frequency in accordance with the July 1987 Statement of Work as referenced by the FMPC QAPP.

Assessing data precision, accuracy, and completeness is an integral part of the data validation process. The laboratories, in accordance with the Statement of Work, discuss in Case Narratives significant problems encountered in the analysis of samples associated with a particular project file. Problems discussed include, but are not limited to: violation of CLP holding time requirements; matrix or non-matrix induced surrogate recovery problems; matrix spike/matrix spike duplicate recovery problems; lack of sufficient sample for full QC; lack of sufficient sample for repreparation of samples, and repreparation of samples outside of holding times due to problems with original preparation. The statement (second paragraph) that the Laboratory should have flagged the results in case 35158 with a "J" is beyond the scope of the Statement of Work. The use of the flag "J" as an estimate qualifier is not part of the Statement of Work. Part B-18 of the July 1987 Statement of Work clearly defines which qualifiers are to be used, and for what purpose. The flag "J" is reserved for validation performed by an independent organization utilizing and having access to the data as it pertains to field identification and location. Rejection, qualification of data other than that specified by the Statement of Work, or acceptance of data is a validation function which can only be performed by those organizations having access to the database and associated field IDs, locations, and results. This validation is currently ongoing at the Project Office.

Additionally, there is a statement that the Laboratory did not conduct several QA procedures required by CLP analytical protocols. The Laboratory, not knowing which specific QA procedures are being referenced by this statement, can only state that those procedures required by the July 1987 Statement of Work in Section E are being followed as required.

Also, in the second paragraph there is a statement that the Laboratory used the ICP method where the GFAA method should have been used. GFAA is now being

used for those elements that do not have the required detection limit for analysis by ICP. These elements include arsenic, lead, selenium, and thallium. Chromium, manganese, and silver meet detection limits required for analyses by ICP. ICP serial dilutions are being performed as required.

The first paragraph on page 4 states that samples should have been flagged "J" by the Laboratory. The use of the "J" flag has addressed above. There is also the statement that it is poor practice to send blanks to one lab and the samples to another, and that QC was referenced to another case for duplicate and matrix spike. This was an isolated incident. It is the policy of the Laboratory to use only client-specific samples for QC analysis, and to run preparation blanks with the samples associated with those blanks.

Organic Analyses

The first paragraph states that holding times for volatiles exceeded the holding times by one day for cases 35155 and 35160, and should have been flagged either "J" or "UJ". These samples were analyzed before the Laboratory received the FMPC QAPP (received by the Laboratory on June 10, 1988). The only document which the Laboratory could follow was the SOW for Organics, since CLP was specified for those samples. The SOW specifies 10 days VTSR holding time for volatiles, which was met by the Laboratory. As was the case with 35158, the Laboratory discusses all problems pertaining to samples in a particular project file in the Case Narrative, in accordance with the Statement of Work. Flagging the data "J" under the SOW for Organics is reserved for qualifying data as estimated for tentatively identified compounds, or where mass-spectral data indicate the presence of a compound that meets identification criteria in which the result is less than the sample quantitation limit but greater than zero. Pages B-23, B-24, and B-25 of the Statement of Work specify which symbols are to be used as qualifiers and what those symbols designate. The use of the flag "J" as an estimate due to holding times is reserved for validation which is to be performed by the organization utilizing the data. The same is true for semi-volatiles and pesticides/PCBs. Rejection, qualification of data other than that specified by the Statement of Work, or acceptance of data is an independent validation function. This validation effort is currently ongoing at the Project Office.

The second paragraph states that samples should have been flagged "UJ". The use of flag "J" has been addressed above. The paragraph also states that surrogate recoveries were low for a particular sample. This was duly noted on the Surrogate Recovery Form 2C, according to the requirements of the Statement of Work.

The third paragraph states that a trip blank was not sent with case 35143. This represents an isolated incident. When samples are received without a trip blank, the field personnel are notified by the Laboratory and corrective measures are taken.

Radiological Analyses

The finding in this section states that there was the presence of low-level contamination in several trip blanks. When these samples are identified on the database during validation, the Laboratory, if requested, will review the results and determine the impact on associated samples.

DATA VALIDATION RESULTS OF ROUND FOUR SAMPLES:

Inorganic Analyses

The use of the "J" flag has been addressed above. The ICP serial dilution results were duly flagged "E" in accordance with the Statement of Work.

The use of flags "N" or "W" for furnace results with low spike recoveries was due to an error in transcription. At that time, the Laboratory generated these documents by hand and some transcription errors were possible. The Laboratory now uses software that generates the forms and flags data where appropriate. In addition, the Laboratory has given tests to analysts performing CLP analyses concerning the use of qualifiers.

The statement in the second paragraph concerning the use of "J" flags has already been addressed. The low spike recoveries were duly noted on Form 5A and Form 1, and were discussed in the Case Narrative. Holding time violations have been reported to the Project Office since January 1989. The Project Office then makes the decision whether or not to analyze or resample.

The finding in the third paragraph concerns the pH of samples. The analysis for pH has been performed since 1989 and has been documented since the early part 1990. These pH analyses are performed by the analysts responsible for analyzing the samples. In addition, field personnel determine the pH of the samples after preservation and attach the pH paper to the bottles. Any problems encountered are documented in a nonconformance memo.

Organic Analyses

The use of the "J" flag has been addressed above.

The finding that there were six pesticides not reported on the database for field ID 03710 is correct in that there were no organic parameters requested on that sample. The EDT for that sample number is enclosed and has no organic results including those of pesticides.

DATA VALIDATION SUMMARY:

Current status on these data validation items is as follows: 1) the revision/resubmittal of the QAPP is in progress; 2) the current data validation program at the FMPC Project Office was discussed, and a copy of the Data Validation Plan provided with our October 12 audit response letter. The effort was also briefly referenced and discussed in this response letter.